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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/791,536 | 03/03/2004 | Lin Shiue Lian | 8961-000010/US | 3361 |
| 30593 | 7590 | 12/19/2006 | EXAMINER | |
| HARNESS, DICKEY & PIERCE, P.L.C. | | | BERTOGLIO, VALARIE E | |
| P.O. BOX 8910 | | | ART UNIT | PAPER NUMBER |
| RESTON, VA 20195 | | | 1632 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 12/19/2006 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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|------------------------------|--------------------------------------|-------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/791,536 | LIAN ET AL. | |
| | Examiner Valarie Bertoglio | Art Unit 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 03/03/04 and 07/02/04 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Applicant's Reply dated 10/03/2006 has been received. Claims 1-24 have been amended. Claims 1-24 are pending and under consideration in the instant office action.

Claim Objections

Claim 23 is objected to because of the following informalities: Claim 23 is directed to the ornamental fish prepared according to the method of claim 1. In light of the teachings in the specification, it is clear that "The ornamental fish" of claim 23 is intended to refer to the fish resulting from carrying out each of the method steps of claim 1 in full (see specification at page 1, lines 5-6; paragraph bridging page 7-8). However, there are multiple fish used in the method of claim 1 as well as that resulting from the full method of claim 1, including a progenitor transgenic fish (step a). Therefore, claim 23 should be written to more precisely indicate what is being claimed, namely the ornamental, transgenic fish resulting from step (c) of claim 1. Alternatively, claim 1 should be amended to more precisely differentiate between the fish used in the method and the progeny resulting from carrying out the method. Appropriate correction is required.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for generating an ornamental fish comprising (a) generating a transgenic oviparous fish whose genome comprises one or more genes encoding a fluorescent protein operably linked to a promoter, wherein the transgene is expressed in the fish; (b) breeding the transgenic

fish with a fish of the same or different species having a phenotype or pattern that differs from the transgenic fish; and (c) screening the resulting transgenic progeny for those showing a phenotype or pattern that differs from each parent and fish made by said method, does not reasonably provide enablement for the claimed method with a transgenic viviparous fish. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is maintained, in part, for reasons of record set forth at pages 2-6 of the previous office action dated 07/03/2006 as outlined below.

Applicant's amendments and arguments have been fully considered and are found partially persuasive. The aspects of the rejection relating to transient transfection and to fish wherein the transgene is not expressed are withdrawn in light of Applicant's amendments to the claims. The claims are now limited to fish whose genome comprises a transgene and also require transgene expression.

Applicant has amended the preamble of claim 1 to read "adult oviparous teleost ornamental fish" however, the method steps differ in scope and fail to limit the species of fish to oviparous species. Thus, the claims continue to encompass use of viviparous fish species, which is not enabled by the specification as set forth at pages 4-5 of the office action dated 07/03/2006. It appears to be Applicant's intention to limit the scope of the claim appropriately and adding the limitation to the body of the claims will be remedial with respect to claim 1. However, claim 17 recites use of a viviparous species, i.e. Livebearing toothcarp, which is not enabled for reasons of record (see pages 4-5 of the office action dated 07/03/2006). While the Examiner has made every effort to discern whether other recited species are viviparous, if Applicant is intending to limit claims to oviparous species, Applicant is requested to remove any remaining viviparous species from the dependent claims.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 11-19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicant's amendment to claim 11.

New grounds of rejection necessitated by amendment are presented below.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

Claim 1 is unclear at step (c) because it does not recite what is to be screened. The claim previously read, "screening the new transgenic progeny". As amended the claim reads "screening for new transgenic progeny" without setting forth what group is to be screened. Language such as "screening the transgenic progeny for those exhibiting..." would be clearer. Claims 2-24 depend from claim 1.

Claim 1 is further unclear because the preamble, as amended, requires that an adult fish be made, however, the method steps fail to make such a requirement. The method steps merely require screening progeny and do not require growth to an adult fish. Thus, the claim is not clearly limited to making an adult fish as indicated by Applicant at page 9, paragraphs 1 and 2 of Applicant's Remarks dated 10/03/2006. Claims 2-24 depend from claim 1.

Claim 17 is unclear as it recites a viviparous species of fish, Livebearing toothcarp, which differs in scope from the oviparous species recited in parent claim 1. To the extent that claim 1 can be interpreted to be limited to oviparous species (see preceding paragraph), claim 17, reciting Livebearing toothcarp, fails to fall within the scope of the parent claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,8,9 and 23 remain rejected and claims 5-7 as amended are newly rejected under 35 U.S.C. 102(b) as being anticipated by Lawson and Weinstein [**Developmental Biology**, 248:307-318].

The rejection is maintained for reasons of record set forth at pages 7-8 of the office action dated 07/03/2006.

Claims 5-7 have been amended to depend from claim 1, necessitating rejection under 35 USC 102(b) for reasons of record at pages 7-8 of the office action dated 07/03/2006. The claims previously depended from claim 4, which is not anticipated by Lawson and Weinstein. Claim 5 now limits claim 1 to a number of specific fluorescent protein encoding genes. Claim 6 and 7 limit claim 1 to a smaller number of specific fluorescent protein encoding genes, each including GFP and EGFP. Lawson and Weinstein taught the use of EGFP in making the fish.

Applicant's arguments have been fully considered but are not persuasive. Applicant has amended claim 1 to require, in the preamble, that the method generate an adult ornamental fish. Applicant argues first, that Lawson and Weinstein did not teach an adult fish that exhibited a phenotype different from either parent. This argument is not persuasive, first, because the claim is not clearly limited to an adult fish as set forth in the rejection under 35 USC 112 2nd paragraph (above). Second, Lawson and Weinstein did teach adult fish (they carried several generations of fish) differing in phenotype and pattern from either parent. Lawson taught mating a pigmented, transgenic fli1::GFP EK strain fish to a mutant albino fish. EK and albino fish have characteristic pigment patterns and resulting progeny would differ from each parent regardless of transgene expression at adult stages. Furthermore, there is no evidence of record

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to indicate that fli1 driven GFP expression would not be observed in the adult progeny as fli1 is expressed in endothelial cells and during vasculogenesis.

Applicant also argues that the fish of Lawson and Weinstein would not have value for ornamental use. Whether the fish would be valuable for ornamental use is subjective. Furthermore, the claims do not pose any requirements for ornamental value or that ornamental value be related to transgene expression or the adult stage of the fish.

Therefore, the rejection is maintained.

The following new rejection is necessitated by the amendment to the preamble of claim 1 reciting that the fish made by the method is an adult.

Claims 1,2,5-9 and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Fadool [Developmental Biology, 258:277-290].

Claims 1 and 2 are drawn to a method of making a fish comprising steps of generating a transgenic fish, breeding said fish to a second fish that has a different phenotype or pattern and screening the transgenic progenies for those exhibiting a phenotype or pattern that differs from either of the parents. Claim 5 limits claim 1 to use of a number of specific fluorescent protein encoding genes including EGFP. Claim 6 and 7 limit claim 1 to a smaller number of specific fluorescent protein encoding genes, each including GFP and EGFP. Claims 8 and 9 limit the phenotype to certain observable morphological phenotypes including body transparency. Claim 23 is limited to the fish made by the method of claim 1. Claim 1 recites a limitation in the preamble that the fish be an adult, however, as set forth above in the rejection under 35 USC 112, 2nd paragraph, the method steps of the claims fail to require any methodology that leads to an adult fish. However, for the purpose of this rejection, the claim is interpreted generically as though it encompasses adult and non-adult fish.

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Fadool taught generating a transgenic EGFP expressing zebrafish using wild-type, pigmented *Danio rerio* (*Brachydanio rerio*) (Ekkwill; page 279, col. 1, paragraph 3). The transgenic EK, pigmented fish were outcrossed to albino mutant *Danio rerio*. The resulting EK/alb transgenic fish, expressing EGFP in the photoreceptors differ from either parent in phenotype and were raised to adulthood to intercross to obtain alb/alb fish expressing EGFP in the photoreceptors (page 280, col. 2, paragraph 1). Albino mutants have an altered body transparent level as a result of a loss of pigmentation. Fadool also taught that adult progeny fish continue to express EGFP in the retina (page 281, col. 1, paragraph 2).

Thus, Fadool taught all of the limitations of claims 1,2,5-9 and 23.

Double Patenting

It is noted that claims 1 and 2 are no longer duplicate claims as claim 2 has been amended to limit the fish used as belonging to the same family, genus or species.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Valarie Bertoglio
Examiner
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